OBJECTIVES: The German market access system for drugs have been changed significantly in the last years, by introducing a similar focus on benefit assessment as in the French system. The research question remains whether they produce consistent results in terms of additional benefit (AB) for pharmaceuticals which have passed the assessment in both systems. **METHODS:** The G-BA and IQWiG as well as the Transparency Commission (TC) databases were searched systematically to identify those products, which have been processed in both systems between Jan 2011 and Dec 2013. For further comparison a data grid consisting of 26 items for evaluation has been developed including study comparator, primary clinical endpoints, health related quality of life inclusion. **RESULTS:** Overall, 140 new therapies have been assessed in France by TC, and 80 in Germany by the G-BA. According to inclusion criteria, 44 products could be identified which have passed through both systems including 7 orphan drugs. Thirteen products (30%) had no AB granted by both Agencies, whereas 9 (20%) were in both cases granted with a minor AB, (assuming that "minor" values are equivalent between the two systems), amounting to 22/44 cases with a similar resolution. Five cases (11%) showed a discrepancy in added benefit, all times TC = no and G-BA = yes. However, varying magnitudes appeared to be the greatest difference (n = 17 (39%) remaining drugs), conditioned by lacking concordance of both scale grade systems. **CONCLUSIONS:** Decisions of the agencies in both countries show partial heterogeneity in driving criteria like benefit levels (ASMR and AB). Although the evidence package for initial assessment in both countries is largely similar, preliminary results suggest their contextualization and scales are different. Further analysis based on results of the grid is needed to better assess criteria leading to different benefit levels and their reimbursement impact.

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FACTORS INFLUENCING DUTCH DRUG REIMBURSEMENT RECOMMENDATIONS; A DATABASE ANALYSIS

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OBJECTIVES: In the Netherlands, manufacturers need to apply for reimbursement of outpatient drugs on either list 1A (no added benefit) or 1B (added benefit). For expensive drugs, hospitals can receive additional reimbursement if the drug is included on the expensive drug list (EDL). Pharmacoeconomic evidence is only required for list 1B and EDL evaluations. The National Health Care Institute (NZi) evaluates submissions and makes (provisional) reimbursement recommendations to the Dutch government. The aim of this study was to identify explanatory variables for the recommendation by NZi. **METHODS:** A database of published evaluations from February-2006 to March-2014 was created, consisting of the final reimbursement recommendation and a range of corresponding explanatory variables such as the therapeutic indication, clinical and economic characteristics. Univariate analyses were performed to assess the impact of the individual explanatory variables on the recommendation by means of odds ratios. **RESULTS:** In total 262 applications were included; the number of positive recommendations by NZi were 121/122 (99%) for 1A, 77/107 (72%) for 1B and 19/28 (68%) for EDL. Pharmacoeconomic analysis was reported in 36/107 (34%) 1B evaluations, of which 27 (75%) were recommended. For the EDL category, pharmacoeconomic analysis was reported in 20/28 (71%) evaluations, out of which 17 (85%) received a positive recommendation. Univariate analyses for the 1B subgroup showed that NZi recommendations were significantly (α=0.05) influenced by clinical trials with life-saving primary endpoint (positive), non-inferior trial outcomes compared to placebo (negative) and budget impact below €2,500,000 (positive). Whereas, the univariate analyses on EDL evaluations demonstrated that ATC-code L (antineoplastic and immunomodulating agents), clinical trials with life-saving primary endpoint and reporting of economic analysis outcomes had a significant and positive impact on the final NZi recommendation. **CONCLUSIONS:** These univariate analyses demonstrated that for 1B and EDL evaluations indication, clinical and economic factors impact the NZi reimbursement recommendations.

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MEASURING EXTENT OF ACCESS FOR NICE HEALTH TECHNOLOGY ASSESSMENT DECISIONS: TRENDS FROM 2008 TO 2013

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OBJECTIVES: When assessing trends in NICE HTA decisions it would be useful to ascertain their implications on access for groups of technologies. A specific issue is to understand the degree of access associated with 'optimised' decisions, where usage has been restricted to a subgroup of patients relative to the scope of the appraisal. Using a previously developed method, we calculate the degree of recommended access for medicines and assess trends between 2008 and 2013 by therapeutic area and over time. **METHODS:** In a previously published paper we developed a measure, **M**, to assess access associated with NICE technology optimised appraisal decisions. This was defined as **M=(p/P)x100**, where **M** is a measure of the level of patient access (0 equals no access, 100 full access), **P** is the set of patients considered in the guidance as potential candidates for treatment (given the scope of appraisal and license), and p is the number of patients for whom NICE did recommend. Applying measure **M** to NICE HTA decisions for medicines between January 2008 and December 2013 we assess trends by therapeutic area and over time. In this paper, to understand trends, we extend the analysis to include recommended and not recommended decisions. We assume a recommended decision scores 100 using measure **M**, a not recommended decision 0, and optimised decisions, where not possible to determine **M**, a score of 50. **RESULTS:** For 201 decisions between 2008 and 2013, on average, **M** was equal to 52, ranging from 37 in 2008 to 57 in 2011. At therapy level, **M** scored between 38 for cancer medicines to 100 for Hepatitis C treatments. **CONCLUSIONS:** The results for this period suggest around half of patients have been recommended by NICE to receive treatment, relative to scope of appraisal and license. These considerations address access not implementation issues.

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A COMPARISON OF INTERNATIONAL HEALTH TECHNOLOGY ASSESSMENT SYSTEMS – DOES THE PERFECT SYSTEM EXIST?

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OBJECTIVES: There are a number of common elements considered good practice in Health Technology Assessment (HTA) that have been published by organizations representing the field. These components include: clear processes and decision-making, including scope for pragmatic approaches and appeal; transparency in methodology, value judgments and decisions; and a facility for stakeholder involvement. The objective of this study was to compare international HTA systems to rank their performance against the ideal components of HTA. Information was also collected on emerging topics such as combined regulatory-payer scientific advice, coverage with evidence, evaluation of drug-diagnostic pairs and disinvestment. **METHODS:** A survey was designed to collect information on the HTA systems in the United Kingdom (UK), France, Germany, Italy, The Netherlands, Sweden, Central Eastern Europe, Canada, Australia, New Zealand (NZ), Korea and Taiwan. Questions were grouped under the topics: process, methods, data, societal input and transparency. The survey was completed by Roche affiliates with first-hand experience working with the HTA system in their country. **RESULTS:** The majority of countries give consideration to rare diseases and low budget impact with leniency in decision making and/or process. Transparency in decision-making is lacking in many of the countries surveyed. Whilst consumer members sit on decision-making committees in several countries, only the UK involves a group of citizens in setting the decision making criteria applied by the committee. Combined regulatory-payer scientific advice is only available in European countries. Australia is the only country to evaluate drug-diagnostic pairings for both costs and outcomes. Only the UK and NZ have routine disinvestment reviews. **CONCLUSIONS:** Each country is performing well in some elements of their HTA system, but none met all the requirements of an ideal system. HTA systems can learn from the experiences in other countries when considering improvements to processes and efficiency.

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TRENDS IN EARLY ENGAGEMENT BETWEEN INDUSTRY AND HTA: ANALYSIS OF SCIENTIFIC ADVICE SERVICE PROVIDED BY NICE SINCE 2009

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OBJECTIVES: Regulatory Scientific Advice (SA) provided by EMA, FDA, MHRA and other agencies is highly demanded by manufacturers but health technology assessment (HTA) scientific advice is still far from becoming a routine step in the product development cycle. NICE has been running an advisory service for 5.5 years. **METHODS:** This work presents analysis of requests to the programme: types of advice projects, number and type of requests per company, clinical indication, stage of clinical development when the advice is sought, reason for seeking advice and current development and regulatory status of products. **RESULTS:** Between 2009 and 2014 NICE conducted 109 advisory projects (107 medicinal products and two diagnostic tests). 23 of these projects were done in parallel with regulatory agencies and/or other HTA bodies. 78% of all requests were in the following four therapeutic areas: oncology, neurology, rheumatology and cardiology. Majority of products (61%) were in phase II of clinical development when advice was sought. At the time of this analysis, 71 products (66%) were still in development, 6 (5.5%) were subject of a review for a marketing authorisation (MA), 8 (7.5%) had received a MA, the authorisation was not granted to 2 products (2%) and the clinical development was discontinued in 20 cases (19%). Most products that received NICE scientific advice are yet to be referred to the technology appraisals programme. **CONCLUSIONS:** Over the last few years, requests for scientific advice diversified into personalised medicines, regenerative medicines and products for rare and very rare diseases. Most HTA scientific advice requests continue to come from top 20 Pharma companies, however we are starting to see an increasing number of inquiries and project bookings from small-medium size companies.

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EXPLORING UNCERTAINTY IN ECONOMIC EVALUATION OF MEDICINES: A REVIEW OF THE FIRST MANUFACTURERS' SUBMISSIONS TO THE FRENCH NATIONAL AUTHORITY FOR HEALTH (HAS)

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OBJECTIVES: Since October 2013, HAS is required to provide the inter-ministerial Economic Committee on Health Care Products (CEPS) with an economic evaluation on innovative medicines likely to have a significant budget impact on the national health insurance scheme. HAS economic evaluations are based on critical appraisals of cost-effectiveness analyses (CEA) submitted by manufacturers. Exploration of uncertainty around incremental cost-effectiveness ratio is critical to assess the robustness of CEA. Our objective was to assess how uncertainty exploration has been undertaken by manufacturers, using HAS guidelines on economic evaluation as an analytical framework. **METHODS:** Manufacturers' submissions assessed by end of May 2014 (n=13) were reviewed. Three sources of uncertainty were considered: uncertainty around model input parameters, uncertainty around model structure and methodological uncertainty. Tools to explore uncertainty included deterministic sensitivity analysis (DSA), probabilistic sensitivity analysis (PSA), as well as overall compliance with HAS guidelines. **RESULTS:** Model input parameters were the most frequently explored source of uncertainty. Both DSA and PSA were systematically used. However, reporting of DSA varied substantially across submissions, with frequent lack of justification of parameters ranges. Regarding PSA, the choice of distribution was not systematically justified and lacked consistency across similar parameters. Most submissions failed to consider parameters correlations. Exploration of uncertainty around model structure was rarely presented. Where applicable, alternative methods for extrapo-